

Faxed : 6-26-01

00274D 49226

2pp

**The Flavor and Fragrance High Production Volume Consortia
(FFHPVC)**

E-028

1620 I Street, N.W.

Suite 925

Washington D.C. 20006

Tel. (202)-293-5800 Fax (202)-463-8998

DRAFT

To: Document Control Office (DCO)
East Tower Room GO99
Waterside Mall
401 M Street SW
Washington, DC 20460

From: Flavor and Fragrance High Production Volume Consortia (FFHPVC)
1620 I Street NW.
Suite 925
Washington, DC 20006

Re: Sponsorship of alpha-Pinene in the Voluntary Children's Chemical Evaluation Program
Document Control Number:OPPTS-00274D

RECEIVED
OPPTS
2001 JUN 29 11:10:49

The Terpene Consortium, as a member of the Flavor and Fragrance High Production Volume Consortia (FFHPVC) currently serves as an industry consortium to coordinate testing activities for alpha-pinene (CAS No. 80-56-8) and other terpene hydrocarbons under the High Production Volume (HPV) "Chemical Right-to-Know" Program. The Terpene Consortium recognizes that alpha-pinene is a constituent of traditional food and occurs naturally as a component of the atmosphere. It occurs widely in fruits and vegetables and food product derived from these sources. As a volatile terpene hydrocarbon, alpha-pinene is continuously emitted into the atmosphere from essentially all plants, but mainly from conifers. Therefore, humans are unavoidably exposed to alpha-pinene through consumption of food and normal inhalation of air. Background levels of alpha-pinene have been detected in human blood plasma, tissue, and body excrements. However, continuous exposure does not result in the accumulation of alpha-pinene in humans in that alpha-pinene is safely metabolized and excreted. Humans have evolved in an environment containing alpha-pinene.

Estimates of biogenic and anthropogenic emissions indicate the human exposure to alpha-pinene is essentially all from biogenic sources. Anthropogenic sources themselves are, in reality, of biogenic origin since turpentine from conifers is the raw material from which the constituent alpha-pinene is isolated. Alpha-pinene itself is a raw material for the preparation many of substances, including those used in food flavors, fragrances, cosmetics, and household products.

Although the producers of alpha-pinene recognize that they make no significant contribution to human exposure to alpha-pinene, they do recognize their responsibility to provide the highest level of product stewardship for this substance. Therefore, the Terpene Consortium will sponsor alpha-pinene in the Volunteer Children's Evaluation Program (VCCEP). That sponsorship will be made under the specific conditions that:

Contain NO CB;

mf 49186

- 1) The responsibilities of the Terpene Consortium will be restricted to a) acceptable completion of testing requirements of the HPV Program and, b) collection of relevant exposure data, and c) preparation of a risk assessment.
- 2) The data from the chemical category designated terpenoid hydrocarbons-pinene group in the HPV Program may be used to complete data requirements under Tier I of the VCCEP.
- 3) The study protocols including routes of administration used in the tests in the HPV Program are acceptable for completion of Tier I testing in VCCEP.
- 4) Because of the vast preponderance of biogenic over anthropogenic generation of this material the Terpene Consortium limits its commitment to Phase I level of the VCCEP. Should the peer review group decide to carry out studies in Phase II or III of the program, a different means of sponsorship will have to be developed that takes into account the biogenic generation of this material.

The Terpene Consortium and its member companies understand that sponsorship entails: assembling and reviewing available test data, development of exposure estimates, preparation of an appropriate risk assessment, and, where needed, conducting additional testing in the time frame established by the Chemical Right-to-Know Program. The Terpene Consortium will begin development of Tier I hazard data and collection of exposure information by December 31, 2001. The anticipated date for submission of a Tier I assessment including additional testing, exposure assessment and risk assessment will be December 31, 2002. Dr. Timothy Adams is the Terpene Consortium's technical contact; he can be reached at 202-331-2325; fax 202-463-8998; email tadams@therobertsgroup.net.

Respectfully,

Timothy B. Adams
Technical Contact Person, FFHPVC